

Annex G

Statement Regarding Chemical and Biological Defense Programs Involving Human Subjects

The reporting requirement (50 USC 1523) for the annual report to Congress on the DoD Chemical and Biological Defense Program was modified by Section 1086 of the FY98 National Defense Authorization Act. The amendment requires the following information:

A description of any program involving the testing of biological or chemical agents on human subjects that was carried out by the Department of Defense during the period covered by the report, together with a detailed justification for the testing, a detailed explanation of the purposes of the testing, the chemical or biological agents tested, and the Secretary's certification that informed consent to the testing was obtained from each human subject in advance of the testing on that subject.

Table F-1 provides a summary of prior and planned tests conducted by the Department of Defense, both directly or under contract, which involve the use of human subjects for the testing of chemical or biological agents. In summary, there has been no such testing since 1969 with biological agents, since 1975 for chemical agents, and no testing is planned.

**Table F-1. Summary of Experiments and Studies with Human Subjects
Involving the Use of Chemical or Biological Agents**

November 25, 1969	– Human biological agent testing ended
July 28, 1975	– Human chemical agent testing ended
Since 1969/1975	– No activities with human subjects involving exposure to biological agents (since 1969) nor chemical agents (since 1975) have occurred since testing ended

The Department is in full compliance with the requirements of all laws regarding the use of human subjects involving chemical or biological agents. DoD is involved in no experimentation or any other efforts which involve the exposure of human subjects to chemical or biological agents.

As part of the DoD Chemical and Biological Defense Program, DoD requires the use of small quantities of chemical and biological agents in the research, development, test and evaluation (RDT&E) of detection, protection, and decontamination equipment and systems. Chemical and biological agents are also used in small quantities in training U.S. forces to operate in protective equipment and to operate detection and decontamination systems in a

chemical or biological environment. However, no RDT&E nor training involves the exposure of human subjects to chemical or biological agents.

Medical chemical and biological defense programs involve the use of human subjects in controlled clinical trials to test and evaluate the safety, immunogenicity, and other effects of medical products (drugs, vaccines, therapies, *etc.*) to protect against chemical and biological agents. The use of human subjects in these trials involves volunteers who have provided informed consent. All use of human subjects in these trials is in full compliance with the “Common Rule,” Federal Policy for the Protection of Human Subjects, Food and Drug Administration (FDA) regulations, Federal Acquisition Regulations (FAR), DoD Directives and Instructions, and *all* other applicable laws, regulations, issuances, and requirements. No medical chemical or biological defense programs involving human subjects involves the exposure of these subjects to chemical or biological agents.

While DoD conducted tests involving the exposure of human subjects to chemical and biological agents in the past, all such tests and programs have been halted and disbanded. The United States formally renounced the “use of lethal biological agents and weapons, and all other methods of biological warfare” in National Security Decision 35, November 25, 1969. Human testing with lethal biological warfare agents was never done and testing with incapacitating biological warfare agents was ceased in 1969. The last human testing of chemical warfare agents occurred on July 25, 1975. Acting Secretary of Army Norman Augustine suspended testing of chemical compounds on human volunteers on July 28, 1975.

Tests involving the exposure of human subjects to chemical agents began in the 1940s and continued following World War II through the Cold War until the early 1970s. Such testing has been documented and reported to Congress. See for example, Department of Army, Inspector General Report, DAIG-IN 21-75, *Use of Volunteers in Chemical Agent Research*, March 1976. In addition, there was extensive Congressional testimony on this subject during 1975 and 1976. DoD has not conducted any experimentation since that time involving the exposure of human subjects to chemical warfare agents.